



1614

Patent Application
Attorney Docket No. PC10607A

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Hon. Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on this 26th day of November, 2003.

By

(Signature of person mailing)

Janice Denison

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Sean Ekins, et al.

APPLICATION NO.: 09/814,442

: Examiner: Marjorie A. Moran

FILING DATE: 03/22/2001

: Group Art Unit: 1614

TITLE: SINGLE POINT INTERACTION SCREEN TO :
PREDICT IC50

Hon. Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. § 1.97 ET SEQ.

Applicant(s) herein make(s) available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820 which lists the references cited by the applicant(s), copies of which are enclosed.

The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).




Patent Application
Attorney Docket No.PC10607A

A prompt and favorable response is earnestly solicited.

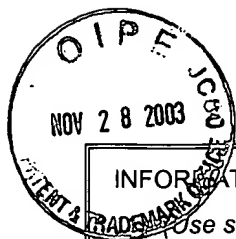
Date: November 26, 2003

Respectfully submitted,

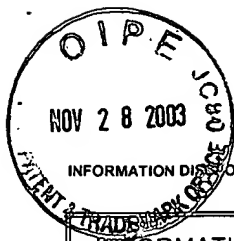


Jennifer A. Kispert
Attorney for Applicant(s)
Reg. No. 40,049

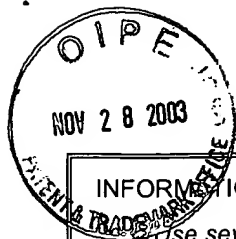
Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 715-5747



INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				ATTY. DOCKET NO. PC10607A				SERIAL NO. 09/814,442									
1 or 4				APPLICANT Sean Ekins				FILING DATE 03/22/2001				GROUP 1614					
U.S. PATENT DOCUMENTS																	
EXAMINER INITIAL		DOCUMENT NUMBER						DATE		NAME		CLASS		SUBCLASS		FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS																	
DOCUMENT NUMBER								DATE		COUNTRY		CLASS		SUBCLASS		TRANSLATION	
																YES NO	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)																	
		/ Banks, M., et al., High throughput screening using fully integrated robotic screening. <i>J Biomolecular Screening</i> 2: 133-135, 1997															
		/ Bertz, R., et al., G. R.: Use of <i>in vitro</i> and <i>in vivo</i> data to estimate the likelihood of metabolic pharmacokinetic interactions. <i>Clin Pharmacokinet</i> 32: 210-258, 1997															
		(Bronson, D., et al., Virtual kinetics: using statistical experimental design for rapid analysis of enzyme inhibitor mechanisms. <i>Biochem Pharmacol</i> 50: 823-831, 1995															
		(Busby Jr, W., et al., Effect of methanol, ethanol, dimethyl sulfoxide, and acetonitrile on <i>in vitro</i> activities of cDNA-expressed human cytochromes P-450. <i>Drug Metab Dispos</i> 27: 246-249, 1999															
		(Chauret, N., et al., Effect of common organic solvents on <i>in vitro</i> cytochrome P450-mediated metabolic activities in human liver microsomes. <i>Drug Metab Dispos</i> 26: 1-4, 1998															
		(Crespi, C., et al., Microtiter plate assays for inhibition of human drug-metabolizing cytochromes P450. <i>Anal Biochem</i> 248: 188-190, 1997															
		(Crespi, C. et al., High throughput screening for inhibition of cytochrome P450 metabolism. <i>Med Chem Res</i> 8: 457-471, 1998															
		- Cronin, M. T., et al, Computer-aided prediction of drug toxicity in high throughput screening. <i>Pharm Pharmacol Commun</i> 4: 157-163, 1998															
		/ Donato, M., et al., A microassay for measuring cytochrome P450IA1 and P450IIB1 activities in intact human and rat hepatocytes cultured on 96-well plates. <i>Anal Biochem</i> 213: 29-33, 1993															
		Draper, A., et al., Inhibition of coumarin 7-hydroxylase activity in human liver microsomes. <i>Arch Biochem Biophys</i> 341: 47-61, 1997															
		Ekins, S., et al., Three dimensional-quantitative structure activity relationship (3D-QSAR) analyses of inhibitors for CYP3A4. <i>J Pharmacol Exp Ther</i> 290: 429-438, 1999															
		Ekins, S., et al., Three dimensional-quantitative structure activity relationship (3D-QSAR) analyses of substrates for CYP2B6 <i>J Pharmacol Exp Ther</i> 288: 21-29, 1999b															
EXAMINER								DATE CONSIDERED									



INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) 2 or 4				ATTY. DOCKET NO. PC10607A				SERIAL NO. 09/814,442						
				APPLICANT Sean Ekins										
				FILING DATE 03/22/2001				GROUP 1614						
U.S. PATENT DOCUMENTS														
EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS														
DOCUMENT NUMBER								DATE	COUNTRY		CLASS	SUBCLASS	TRANSLATION	
													YES	NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)														
			Ekins, S., et al., Autoactivation and activation of cytochrome P450s. <i>Int J Clin Pharmacol Ther</i> 36: 642-651, 1998											
			FDA: Guidance for industry. Drug metabolism/drug interaction studies in the drug development process: studies in vitro. , 1997											
			FDA: Guidance for industry. In vivo drug metabolism/drug interaction studies - study design, data analysis, and recommendations for dosing and labeling. , 1998											
			Fuhr, U., et al., Systematic screening for pharmacokinetic interactions during drug development. <i>Int J Clin Pharmacol Thera</i> 34: 139-151, 1996											
			Hickman, D., et al., Evaluation of the selectivity of in vitro probes and suitability of organic solvents for the measurement of human cytochrome P450 monooxygenase activities. <i>Drug Metab Dispos</i> 26: 207-215, 1998											
			Hook, D.: Ultra high-throughput screening - a journey into nanoland with Gulliver and Alice. <i>Drug Discovery Today</i> 1: 267-268, 1996											
			Ito, K., et al., Prediction of pharmacokinetic alterations caused by drug-drug interactions: metabolic interaction in the liver. <i>Pharmacol Rev</i> 50: 387-411, 1998											
			Korfmaier, W., et al., HPLC-API/MS/MS: a powerful tool for integrating drug metabolism into the drug discovery process. <i>Drug Discovery Today</i> 12: 532-537, 1997											
			Kronbach, T., et al. High performance liquid chromatography assays for bufuralol 1'-hydroxylase, debrisoquine 4-hydroxylase and dextromethorphan O-demethylase in microsomes and purified cytochrome P-450 isozymes of human liver. <i>Anal Biochem</i> 162: 24-32, 1987											
			Leeman, T., et al., Cytochrome P450TB (CYP2C): A major monooxygenase catalyzing diclofenac 4'-hydroxylation in human liver. <i>Life Sci</i> 52: 29-34, 1992											
			Lin, J., et al., Inhibition of cytochrome P-450 and implications in drug development. <i>Ann Rep Med Chem</i> 32: 295-304, 1997											
EXAMINER			DATE CONSIDERED											



INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				ATTY. DOCKET NO. PC10607A				SERIAL NO. 09/814,442							
				APPLICANT Sean Ekins				FILING DATE 03/22/2001				GROUP 1614			
3 of 4				U.S. PATENT DOCUMENTS											
EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
FOREIGN PATENT DOCUMENTS															
DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
												YES NO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)															
		Lin, J., et al., Inhibition and induction of cytochrome P450 and the clinical implications. <i>Clin Pharmacokinet</i> 35: 361-390, 1998													
		Lutz, M., et al., Experimental design for high-throughput screening. <i>Drug Discovery Today</i> 1: 277-286, 1996													
		Maenpaa, J., et al., Human cytochrome P4503A (CYP3A) mediated midazolam metabolism: the effect of assay conditions and regioselective stimulation by a-naphthoflavone, terfenadine and testosterone. <i>Pharmacogenetics</i> 8, 1998													
		Miwa, G. T., et al., Goals, design, timing, and future opportunities for non clinical drug metabolism studies. <i>Toxicol Pathol</i> 23: 131-135, 1995													
		Pichard, L., et al., Screening for inducers and inhibitors of cytochrome P-450 (cyclosporin A oxidase) in primary cultures of human hepatocytes and in liver microsomes. <i>Drug Metab Dispos</i> 18: 595-606, 1990													
		Rodrigues, A., et al., Preclinical drug metabolism in the age of high-throughput screening: An industrial perspective. <i>Pharm Res</i> 14: 1504-1510, 1997													
		Rodrigues, A., et al., [O-ethyl 14C] phenacetin O-deethylase activity in human liver microsomes. <i>Drug Metab Dispos</i> 25: 1097-1100, 1997													
		Shimada, T., et al., Interindividual variations in human liver cytochrome P-450 enzymes involved in the oxidation of drugs, carcinogens and toxic chemicals: studies with liver microsomes of 30 Japanese and 30 Caucasians. <i>J Pharmacol Exp Pharmacol</i> 270: 414-423, 1994													
		Singh, J., et al., Lead development: validation and application of high throughput screening for determination of pharmacokinetic parameters for enzyme inhibitors. <i>Bioorg Med Chem</i> 4: 639-643, 1996													
		Sittampalam, G., et al., Design of signal windows in high throughput screening assays for drug discovery. <i>J Biomolecular Screening</i> 2: 159-169, 1997													
		Smith, D., et al., Human cytochrome P450s: selectivity and measurement in vivo. <i>Xenobiotica</i> 28: 1095-1128, 1998													
EXAMINER				DATE CONSIDERED											

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO. PC10607A	SERIAL NO. 09/814,442
---------------------------------	---------------------------	-----------------------



(Use several sheets if necessary)

4 of 4

APPLICANT Sean Ekins

FILING DATE 03/22/2001

GROUP 1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Sonderfan, A., et al., Regulation of testosterone hydroxylation by rat liver microsomal cytochrome-P450. <i>Arch Biochem Biophys</i> 255 : 27-41, 1987.
		Spencer, R., High-throughput screening of historic collections: observations on file size, biological targets and file diversity. <i>Biotechnol Bioeng</i> 61 : 61-67, 1998
		Tarbit, M., et al., High-throughput approaches for evaluating absorption, distribution, metabolism and excretion properties of lead compounds. <i>Curr Opin Chem Biol</i> 2 : 411-416, 1998
		Tucker, G., et al., The rational selection of drug interaction studies: implications of recent advances in drug metabolism. <i>Int J Clin Pharmacol Thera Toxicol</i> 30 : 550-553, 1992
		van der Hoeven, T., et al., Preparation and properties of partially purified cytochrome P-450 and reduced nicotinamide adenine dinucleotide phosphate-cytochrome P450-reductase from rabbit liver microsomes. <i>J Biol Chem</i> 249 : 6302-6310, 1974
		van der Voet, H.: Comparing the predictive accuracy of models using a simple randomization test. <i>Chem Int Lab Systems</i> 25 : 313-323, 1994
		Wrighton, S., et al., The use of in vitro metabolism techniques in the planning and interpretation of drug safety studies. <i>Toxicologic Pathology</i> 23 (2): 199-208, 1995
		Wrighton, S., et al., In vitro methods for assessing human hepatic drug metabolism: their use in drug development. <i>Drug Metab Rev</i> 25 (4): 453-84, 1993
		Wynalda, M., et al., Assessment of potential interactions between dopamine agonists and various human cytochrome P450 enzymes using a simple in vitro inhibition screen. <i>Drug Metab Dispos</i> 25 : 1211-1214, 1997

EXAMINER

DATE CONSIDERED